

REMARKS

Applicants respectfully request consideration of the foregoing amendments and the following commentary upon reexamination of the present application on the merits.

I. Introduction

The Examiner acknowledges that the amendments to claims presented in the response filed on September 29, 2008 have been entered (see Advisory Action). Claim 18 was previously cancelled. Claims 1, 19, 37 and 57 also have been amended to replace “comprising” with “consisting essentially of” to better distinguish the claimed invention from the cited art.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-17 and 19-57 will be pending, with claims 27 and 31-36 withdrawn from consideration.

II. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-17, 19-26, 28-30, and 37-57 are rejected under 35 U.S.C. §103(a) for alleged obviousness over U.S. Patent No. 6,287,596 to Murakami et al. (“Murakami”). Applicants respectfully traverse the rejection.

Murakami discloses a rapidly disintegratable composition, which requires the presence of a mixture of erythritol and an excipient (column 4, lines 6-20). Particularly, the amount of erythritol and the excipient must fall within a certain range. Murakami further describes that “[a]mounts [of erythritol and the excipient] less than 30% by weight lead to insignificant contribution of these ingredients, resulting in poor disintegration and dissolution” (column 5, lines 32-39).

In contrast, the claimed invention is directed to a solid dosage form having a friability of less than about 1%. The claimed solid dosage form comprises at least one active agent and

pullulan in the range of about 99.9% to about 0.1% (w/w). Therefore, the claimed invention is distinguished from Murakami in at least the following aspects: (i) the prior art does not teach or suggest a composition having a friability of less than about 1%; (ii) the claimed dosage form does not require the presence of erythritol, which is mandatory for the prior-art composition; and (iii) the claimed dosage form requires the presence of pullulan, which is only an optional additive for the prior-art composition (see Murakami, column 7, lines 10-12 and 28).

The Examiner contends that the above arguments are not persuasive “because the comprising language of the claims is open” (Advisory Action, page 2, lines 2-3). The claims have been amended to recite a solid dosage form “consisting essentially of” at least one active agent and pullulan, thereby distinguishing from the compositions of the prior art.

Furthermore, “[b]y using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that ***do not materially affect the basic and novel properties of the invention.***” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351 (Fed. Cir. 1998) (emphasis added).

In the present application, the dosage forms of the invention may further comprise a pharmaceutically acceptable sugar, plasticizer, effervescent agent, or excipient, as recited in claims 4-11 and 40-47, which does not materially affect the claimed dosage forms. Accordingly, the claims at issue are also non-obvious over the cited art.

The Examiner asserts that “friability is a property of the product” (final Office Action, page 3, line 18). Pursuant to MPEP 2112, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).” Nevertheless, because the claimed dosage form is distinguished from the

prior-art composition in their ingredients, the Examiner has not established an “inherency” in the present case.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under Section 103(a).

III. Rejection of Claims under 35 U.S.C. §112, second paragraph

Claims 13 and 49 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. In the Advisory Action, the Examiner acknowledges that the rejection has been withdrawn in view of the arguments in the prior response to the final Office Action.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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